

510(k) Summary

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General Provisions

Submitter's Name and
Address

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Contact Person

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OCT 1 ~ 2007

Date of Summary

September 18, 2007

Proprietary Name of Device

Sleuth Implantable ECG Monitoring System

Common/Usual Name

Implantable ECG Monitoring System

Classification Name

Cardiac Implantable Event Recorder
Product Code – MXC
Regulation Number 21 CFR Part 870.2800
Device Class II

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed

Medtronic, Inc., Reveal[®] Plus Insertable
Loop Recorder (ILR) System (K003667,
K994331 and K972242)

Brentwood Medical Technology Corporation
– IQmark[™] Digital Holter, (K031466)

Device Description

The Transoma Medical Sleuth Implantable ECG Monitoring System is designed to measure and store the patient's electrocardiogram (ECG) during symptomatic and asymptomatic events. The Sleuth System consists of the Model 2010 Implantable Monitoring Device (IMD), the Model 4000 Activator, and the Model 5000 Base Station (Bluetooth Modem). The IMD is an anatomically-shaped titanium structure which is implanted subcutaneously, typically in the left pectoral region. The Activator is a hand-held device carried by the patient.

The IMD continuously measures the R-R interval and automatically stores ECG segments when this interval falls outside of pre-defined limits. Using the Activator, the patient can also request storage of ECG segments when symptoms are experienced. The IMD stores a limited quantity of events, which are transferred to the Activator via telemetry throughout the day. On a daily basis, the Activator transfers events through the Base Station to a service center for review and analysis.

Intended Use

The Transoma Medical Sleuth 2010 System is an implantable, patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias or
- patients who experience transient symptoms that may suggest a cardiac arrhythmia.

Summary of Technological Characteristics

The Transoma Medical Sleuth 2010 System incorporates substantially equivalent technology, comparable features, labeling, and intended use, and is similar to the predicate devices currently available on the market.

Non-clinical Test Summary

The substantial equivalence of the Transoma Medical Sleuth 2010 System has been demonstrated via bench and animal testing. Testing included:

- In vitro/ bench testing of the IMD, the Activator, the Base Station and the system
- In vivo canine testing
- Biocompatibility testing
- Software testing
- Electromagnetic compatibility testing
- Electrical safety testing
- Sterilization validation
- Shelf-life testing

Clinical Study Summary

A clinical study was conducted at 4 major medical centers in Panama. The primary objectives were to evaluate the diagnostic viability of the ECG signals and the performance of the system. Twenty-eight (28) patients were enrolled in the study. The patients had unexplained syncope/ pre-syncope or were at risk of arrhythmias. Patients were monitored continuously (24/7) by the Sleuth device for arrhythmic events. Clinic follow-ups were 7-10 days, 1, 3, and 6 months after implantation.

The cardiac monitoring center has been able to analyze and categorize the ECG waveform data. The Sleuth system has successfully captured events initiated manually, as well as asymptomatic events which are detected and recorded automatically by the system. As designed, the Sleuth system has also successfully stored and transferred trending data.

The Sleuth ECG system has performed well following implantation in the initial 28 patients. The system has diagnostic viability, since thirteen of the patients were discovered during monitoring to have arrhythmias, and the Sleuth records were important in helping the physicians arrive at a firm diagnosis. The occurrence of two adverse events within > 4,700 collective patient days of use is within expectation, and these events were neither serious, nor definitively shown to derive from the Sleuth system.

Performance Standards

Performance standards have not been established by the Food and Drug Administration for these devices under Section 514.

Conclusion (Statement of Equivalence)

Extensive bench and animal testing have demonstrated the Sleuth Model 2010 System functions in accordance with product specifications. Additionally, testing demonstrated the Sleuth System functions equivalently to comparative systems, i.e., the Brentwood IQmark Digital Holter (K031466) and the Medtronic Reveal Plus Insertable Loop Recorder (K003667, K994331 and K972242). These data

support a determination of substantial equivalence and subsequently market clearance of the Transoma Medical Sleuth System, comprised of the Model 2010 IMD, Model 4000 Activator, and Model 5000 Base Station.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Transoma Medical, Inc.
c/o Ms. Angie Raun
Vice President
Regulatory Affairs and Quality Assurance
4358 West Round Lake Road
Arden Hills, MN 55112

OCT 1 2007

Re: K063035
Trade/Device Name: Sleuth Implantable ECG Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC
Dated: June 29, 2007
Received: July 2, 2007

Dear Ms. Raun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number K063035

Device Name: Transoma Medical Sleuth Implantable ECG Monitoring System

Indications for Use:

The Transoma Medical Sleuth Implantable ECG Monitoring System is an implantable, patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

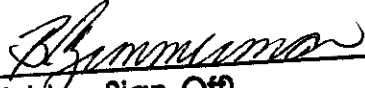
Prescription Use X
(21 CFR 801 Subpart D)

OR

Over The Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063035